DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PRODUCT LICENSE APPLICATION FOR MANUFACTURE OF ANTI-HUMAN GLOBULIN

Form Approved: OMB No. 0910-0124.
Expiration Date: November 31, 2001.
See Page 4 For OMB Statement.

DATE SUBMITTED

GENERAL INSTRUCTIONS

Type or print legibly in ink. Complete all items. Items which are not applicable, enter "NA". If more space is needed for any item, continue on an 8 1/2 x 11 inch sheet, reference the entry by item number, and attach. Allow 1 inch top margin for filing purposes. Submit the original and one copy of the completed application. Assemble and staple each set, including all attachments. The application forms must be dated and signed by the responsible head. Return this application to DHHS/PHS, FDA/Director, Center for Biologics Evaluation and Research (HFM-370), 1401 Rockville Pike, Rockville, MD 20852-1448.

One form may be used for each group of products which are from the same animal source and are manufactured and tested in a similar manner. Include three copies of all labeling (drafts, printers proofs, or final printed, including bulk export labeling) which will accompany the product (use Form FDA-2567 "Transmittal of Labels and Circulars"). Submit one copy of each applicable processing and testing record with sample entries.

NOTE: No license for the manufacture of Anti-Human Globulin may be granted unless this completed form has been received by FDA. (U.S. Public Health Service Act, Section 351; The Federal Food, Drug and Cosmetic Act, Section 502; and Title 21, U.S. Code of Federal Regulations, part 600).

GENERAL INFORMATION

1. MANUFACTURER'S NAME, ADDRESS, AND ZIP CODE

TELEPHONE NO. *(Include area code)*

2. ESTABLISHMENT NAME, ADDRESS, AND ZIP CODE *(If different from Item 1)*

TELEPHONE NO. *(Include area code)*

3. PRODUCTS COVERED BY THIS APPLICATION *(CHECK ALL APPLICABLE)*

- ☐ HEAVY CHAIN SPECIFIC, ANTI-IgG
- ☐ ANTI-IgG, NOT HEAVY CHAIN SPECIFIC
- ☐ ANTI-C3d
- ☐ ANTI-C3
- ☐ ANTI-C4
- ☐ ANTI-C3 + C4
- ☐ POLYSPECIFIC, LIST ACTIVITIES CLAIMED _____
- ☐ OTHER _____

4. ANIMAL SOURCE OF BLOOD FROM WHICH PRODUCT IS PROCESSED

5. DESCRIBE AND GIVE SPECIFICATIONS FOR PURITY OR HOMOGENEITY OF THE IMMUNIZING AGENT

- ☐ PREPARED-IN HOUSE
- ☐ PURCHASED

5a. PURCHASED FROM

5b. IF PURCHASED, DESCRIBE QUALITY CONTROL PROCEDURES USED TO DETERMINE SUITABILITY

6. DESCRIBE ALL STEPS IN PROCESSING SERA *(Including storage temperature of raw plasma or sera).* May be submitted as SOP Manual or "Flow Sheet" showing manufacturing steps chronologically, reagents added, etc., through finished bulk and filling of final containers. Answers to the following questions must also be included.

6a. WHAT TEST ARE DONE ON THE RAW SERA TO DETERMINE THEIR SUITABILITY FOR USE IN MANUFACTURING?	6b. IF THE RAW SERA ARE ABSORBED, OUTLINE THE METHOD THAT IS USED.
6c. HOW IS THE DILUTION FACTOR DETERMINED FOR EACH COMPONENT? *(Is an in-house standard used for comparison?)*	6d. IF THE PRODUCT IS POLYSPECIFIC GIVE THE APPROXIMATE POOLING RATIO FOR THE ANTI-IgG AND THE ANTICOMPLEMENT COMPONENTS.
6e. IF THE ANTIBODY NITROGEN LEVEL IS MEASURED, WHAT METHOD IS USED AND WHAT N_2 LEVEL IS THE PRODUCT STANDARDIZED?	
7a. AVERAGE LOT SIZE *(In ml)*	7b. HOW MANY *(average number and range)* ANIMALS ARE USED TO PREPARE EACH ANTI-HUMAN GLOBULIN POOL *(lot)*?
8a. DESCRIBE DILUENT USED FOR EACH PRODUCT ID ANY SERA ARE DILUTED *(Include the concentration of each ingredient in the final product)*	
8b. IF BOVINE SERUM ALBUMIN IS USED IN THE PRODUCT, LIST THE SOURCE AND DESCRIBE YOUR QUALITY CONTROL PROCEDURES FOR DETERMINING ITS SUITABILITY FOR USE IN MANUFACTURING ANTI-HUMAN GLOBULIN	
9. PRESERVATIVE AND CONCENTRATION USED IN FINAL PRODUCT	
10. COLORING AGENTS USED, FINAL CONCENTRATION	
11. METHOD OF STERILIZING FINAL CONTAINERS AND CLOSURES	
12. DESCRIBE STERILITY TEST	

13a. DESCRIBE POTENCY TEST FOR EACH PRODUCT

13b. DESCRIBE ANY OTHER REACTIVITY TEST THAT ARE DONE

14. DESCRIBE THE STABILITY TEST, IF ANY, ROUTINELY PERFORMED TO MONITOR THE PERFORMANCE OF THE PRODUCT DURING ITS SHELF LIFE

15. DESCRIBE SPECIFICITY TESTS FOR EACH PRODUCT

16. WHAT SIZE VIALS OF EACH PRODUCT ARE MARKETED?

17. DESCRIBE FINAL CONTAINER IDENTITY TESTS FOR EACH PRODUCT

18a. DESCRIBE COLLECTION OF QUALITY CONTROL SAMPLES

18b. LIST FINAL PRODUCT LIMITS FOR SALT AND PROTEIN CONCENTRATION AND pH

19. DESCRIBE COLLECTION OF SAMPLES SUBMITTED TO THE OFFICE

20. DESCRIBE STORAGE CONDITIONS *(Including temperature)* OF PRODUCT PRIOR TO LABELING, INCLUDING BULK OR UNLABELED VIALS

21. DESCRIBE LABELING AND PACKAGING CONTROLS INCLUDING RESPONSIBILITY FOR ASSIGNMENT OF EXPIRATION DATES AND SELECTION OF PACKAGE INSERTS

CERTIFICATION

I certify that all statements made in this application are true and correct to the best of my knowledge and ability. I am familiar with the pertinent Sections of Title 21, Code of Federal Regulations, and am aware of my responsibilities described herein.

WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

TYPED NAME OF RESPONSIBLE HEAD	SIGNATURE OF RESPONSIBLE HEAD	DATE

REMARKS